

The Omnipod® 5 Automated Insulin Delivery System is available through the pharmacy!

Omnipod 5 offers a simple and freeing alternative to multiple daily injections and tethered tubed pumps. Omnipod 5 is an on-body automated insulin delivery system consisting of a wearable Pod with an embedded algorithm and a Dexcom G6 continuous glucose monitoring sensor. Smartphone control is available. Patients without compatible smartphones are required to use the Controller provided with the Intro Kit*.

Patient Type

Cleared for use for the management of Type 1 diabetes mellitus in persons aged two years or older.¹

Insulin Choice

U-100 short-acting insulin used for both basal and bolus doses. NovoLog®, Humalog®, and Admelog® are cleared for use within the Pod.

HOW TO PROCESS THE SCRIPTS

Omnipod 5 G6 Intro Kit (Gen 5)

NDC 08508-3000-01

One-time only script, no refills, includes:

- 10 Pods—Two 5-Packs
- Controller



Omnipod 5 G6 Pods (Gen 5)

NDC 08508-3000-21

Refill 5-Packs. Prescribed and filled to patient insulin requirements:

- **2 boxes/month** = 30-day supply for a 72-hour change-out
- **3 boxes/month** = 30-day supply for a 48-hour change-out



HOW TO SET UP REQUIRED TRAINING



A requisite for new users either virtually or in-person (*individualized setup*).

To schedule their training, new users **must** contact Omnipod at **1-800-591-3455** or visit **omnipod.com/setup**.

The Omnipod 5 System

Pod Features

- **Tubeless, wearable, waterproof² Pod** with embedded algorithm integrated with **Dexcom G6[®] CGM**
- Pod includes a 200-unit reservoir for **up to 72 hours of continuous insulin delivery** (*insulin not included with Pod*)
- **Automatic** cannula insertion and priming
- **System control** from a compatible smartphone*

Software Features

- **SmartAdjust™ technology** automatically adjusts insulin delivery every 5 minutes to manage blood glucose—algorithm predicts where the glucose will be in 60 minutes and **proactively increases, decreases, or pauses insulin delivery**.
- **Customizable Target Glucose Settings** from 110-150 mg/dL in 10mg/dL increments—**user can set target by time of day**
- **SmartBolus Calculator** informed by **CGM value and trend**
- **Activity feature used during exercise** adjusts the glucose target to 150 mg/dL and reduces insulin delivery when glucose typically goes low



Pod and Dexcom G6 shown without necessary adhesive.

Omnipod 5 Pod
(Insulin not included)

Controller or compatible smartphone with Omnipod 5 App

(Dedicated Omnipod 5 handheld Controller is also provided in Intro Kit)

Dexcom G6[®] CGM

(Sold separately and requires separate script. Dexcom app required for use.)

*For a list of compatible smartphone devices, visit omnipod.com/compatibility.

Omnipod 5 Access & Coverage

Insurance Coverage

Omnipod 5 has pharmacy coverage for **over 300 million lives³**

Pharmacy Accessibility

More than 26,000 US pharmacies have dispensed Omnipod 5.⁴

Patient Cost

The majority of Omnipod 5 customers **pay \$50 or less per month.⁵**



Omnipod 5 with SmartAdjust™ Technology—Demonstrated Clinical Results

Reduced HbA1c by **0.38%**
in adults/adolescents,
0.71% in children aged 6+ and **0.55%**
in preschool-aged (2-5.9) children^{1,6}

Increased Time in Range to **74%**
in adults/adolescents,
68% in children aged 6+ and **68.1%**
in preschool-aged (2-5.9) children^{1,6}

Reduced Time Below Range by **46%**
in adults/adolescents and **remained low**
in children ages 2+^{1,6}

In a 3-month clinical study, during Omnipod 5 system use, there were 3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) in children & adults/adolescents. In another 3-month study in preschool-aged (2-5.9) children there were no cases of severe hypoglycemia or DKA. **These cases were not related to automated insulin delivery malfunction^{1,6}.**

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Important Safety Information for Omnipod® 5:

The Omnipod 5 Automated Insulin Delivery System is indicated for use by individuals with Type 1 diabetes mellitus in persons 2 years of age and older. The Omnipod 5 System is intended for single patient, home use and requires a prescription. The Omnipod 5 System is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

The Omnipod 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 SmartBolus Calculator is intended to calculate a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (*or blood glucose reading if using fingerstick*), rate of change of the sensor glucose (*if applicable*), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value.

Warning: SmartAdjust™ technology should NOT be used by anyone under the age of 2 years old. SmartAdjust™ technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.

The Omnipod 5 System is NOT recommended for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, are unable to use the Omnipod 5 System according to instructions, are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders. Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components. Visit www.omnipod.com/safety for additional important safety information.

Sources: 1. Sherr JL, et al. Prospective trial in 80 participants with T1D aged 2-5.9 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop (HCL) phase. Mean overnight time >180 mg/dL (12AM-6AM) as measured by CGM: ST = 38.4%, 3-mo Omnipod 5 = 16.9%, P<0.001. Mean daytime >180 mg/dL (6AM-12AM) as measured by CGM: ST = 39.7%, 3-mo Omnipod 5 = 33.7%, P<0.001. Median overnight time in <70 mg/dL (12AM-6AM) as measured by CGM: ST = 3.41%, 3-mo Omnipod 5 = 2.13%, P=0.0185. Median daytime <70 mg/dL (6AM-12AM) as measured by CGM: ST = 3.44%, 3-mo Omnipod 5 = 2.57%, P=0.0799. 2. The Pod has an IP28 rating for up to 25 feet for 60 minutes. The Controller is not waterproof. 3. Reflects total Omnipod 5 unique pharmacy dispensing count. Source: Insulet Data on File as of June 1, 2023. 4. Reflects total Omnipod 5 unique pharmacy dispensing count. Source: Insulet Data on File as of June 1, 2023. 5. Calculated based on a consumption of ten (10) Pods per month. Majority defined as at least 70% of patient co-pays \$50 or less per month. Among All Paid Omnipod 5 G6 Pods Commercial and Medicare Claims from August 2022 through July 2023. Includes benefits and offerings available through Insulet, such as the copay card program. Actual co-pay amount depends on patient's health plan and coverage, they may fluctuate and be higher or lower than the advertised amount on a monthly basis. Source: IQVIA OPC Library. 6. Brown S, et al. Prospective pivotal trial in 240 participants with T1D aged 6-70 yrs [adults/adolescents (n=128; aged 14-70 yrs) children (n=112; aged 6-13.9 yrs)]. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop phase. Mean overnight time >180 mg/dL (12AM-6AM) as in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 32.1% vs. 20.7%; 42.2% vs. 20.7%, P<0.0001, respectively. Mean day time >180 mg/dL (6AM-12AM) in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 32.6% vs. 26.1%; 46.4% vs. 33.4%, P<0.0001, respectively. Median overnight time in <70 mg/dL (12AM-6AM) in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 2.07% vs. 0.82%, P<0.0001; 0.78% vs. 0.78%, P=0.0456, respectively. Median day time <70 mg/dL (6AM-12AM) in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 1.91% vs. 1.08%, P<0.0001; 1.17% vs. 1.62%, P=0.2545, respectively. Outcomes measured by CGM.

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